

## ABSTRACT OF DISCLOSURE

An automated peritoneal dialysis system for performing continuous peritoneal dialysis is disclosed which includes a supply of unsterilized dialysate for supplying large volumes of dialysate on demand; a fluid circuit for delivering dialysate from the supply to the patient's peritoneal cavity and draining spent dialysate from the peritoneal cavity. A dialysate sterilization component includes at least one in-line sterilization filter assembly disposed in the inflow line segment for realtime sterilization of the unsterilized dialysate during flow of dialysate prior to patient delivery. A filter test component is operatively associated with the sterilization filter assembly for conducting a realtime integrity test on the filter assembly to test for a filter failure which would allow contaminants into the dialysate prior to patient delivery. In this manner, large volumes of sterilized dialysate are available on demand in realtime during the peritoneal dialysis process to provide a high rate of dialysate exchange during repeated dialysate fill and drain cycles until a desired amount of fluid and waste is removed from the patient. The fluid circuit includes a discard line segment for discarding dialysate passed through the filter assembly in the event the filter medium fails the integrity test. Preferably a delivery vessel is connected to the sterilization filter assembly for accumulating the sterilized dialysate prior to delivery to the patient, and the discard line segment is connected to the delivery vessel wherein the integrity test is conducted after the sterilized dialystate has been delivered to the delivery vessel and prior to delivery of the dialysate to the patent. Advantageously, the sterilization filter assembly constitutes a first sterilization filter assembly; and the system includes a second sterilization filter assembly connection to

the first sterilization filter assembly through which dialysate flows from the delivery vessel to the patient. A pretest is done on the second filter assembly while the post-test is done on the first filter assembly. An automated peritoneal dialysis process is disclosed for performing continuous peritoneal dialysis which includes (a) providing a generally uninterrupted supply of large volumes of unsterilized dialysate; (b) passing said unsterilized dialysate from the supply through an in-line sterilization filter assembly to produce sterilized dialysate in realtime during the process prior to delivery to the patient's peritoneal cavity; (c) accumulating sterilized dialysate in a delivery vessel prior to delivery to the patient; (d) subjecting the in-line filter assembly to a realtime filter integrity test during the process to test for a filter failure that would allow contaminants into the dialysate prior to patient delivery; (e) delivering said sterile dialysate from said delivery vessel to the patient's peritoneal cavity after said filter integrity test is passed; and (f) repeating steps (a) through (e) until a desired volume of dialysate is exchanged.

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